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EXAMINER
WESSENDORF, T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1627 | 10 |

DATE MAILED: 04/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/331,808

Applicant(s)
Lindqvist et al

Examiner
T. Wessendorf

Group Art Unit
1627



☒ Responsive to communication(s) filed on 1/11/01

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-18 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons set forth in the last Office action.

It is argued that the skilled artisan is provided with a number of exemplary proteins possessing the claimed functional property. Applicants point out that the invention is not restricted to any particular cis-acting protein or fragment thereof. Rather, the invention is directed generally to methods of producing libraries that express peptides or protein and that makes use of the property of a subset of proteins that bind covalently to their own coding DNA. It is further urged that one skilled in the art would not require any additional written description beyond the disclosure of the present specification in

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order to identify peptides or proteins according to the present claimed invention.

Without a description of the protein, for example, not to mention the fragment, derivatives or variants, one is left to speculate as to the protein that suits the instant method. The numerous prior art provided in the background of the invention clearly describes and demonstrates, at the time of filing, that only specific components e.g., protein library can be produced by a specific method suited for said particular library. Assuming, for the sake of arguments, that one is able to produce a library of not a single protein, but a "diverse population" of proteins of undefined kind, length, structure and etc. still, the formidable task of screening or finding a screening method that would suit a diverse population of e.g., peptide or protein is not adequately described.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

A). It is argued that diverse population is used in the present claims may relate to proteins that are diverse in any respect. This argument does not clarify the indefiniteness of a diverse population and fails to circumscribe the boundaries of a diverse population.

B). The rejection(not objection as argued) is withdrawn in view of applicants' arguments.

C). Applicants request clarification as to the claims rejected under this paragraph. As stated by applicants at page 5 of the REMARKS only claims 9 and 10 contain the rejected term "modified". Applicants argue that page 11 recites for in vitro translation that allows the incorporation of many co- and post-translational modifications. Applicants further argue that said term encompasses, inter alia, both chemical and enzymatic modifications. Applicants mer/arguments do not render the claims definite, absent support in the specification. Thus, the metes and bound of the claimed modified is indefinite. The argued

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specification definition of post-translational modification does not clearly set forth the metes and bounds of the claimed term.

The following rejections are applicable to the newly presented claims:

1). Claim 1 is indefinite as to whether the phrase "having at least one site of attachment for the binding moiety" refers to the sequence encoding the display moiety. (Cf. with the specification and original claim).

2). Claim 14 is indefinite for failure to define the metes and bounds of the desired properties exhibited especially since the library, as applicants assert, is composed of diverse population of library members of infinite kind, length and etc.

3). Claim 19 is indefinite because of the inconsistency between the preamble and body of the claims. The preamble recites purification of a library member, The body recites only selecting and isolating without purification step.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 7-9, 11-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mattheakis et al (5,922,545) for reasons advanced in the last Office action.

Applicants admit that the only reference of Mattheakis to covalent binding is that between an immunoglobulin to mRNA serving as the translation template or to a cDNA copy thereof. It is further admitted that other tether segments include biotin/streptoavidin specific binding pairs. But argue that the present invention relates to the covalent binding of a peptide or protein to its encoding DNA. The tether segment of Mattheakis, as admitted by applicants and described by Mattheakis relates to covalent binding of the specific protein, immunoglobulin (Ig) to

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the translating (encoding, as claimed) DNA. See further col. 16, lines 42-49 as to the definition of tether segment and col.15, lines 45-55 of nascent polypeptide. The disclosure of Mattheakis relating to tether segment or fusion protein between the encoding DNA and protein its encodes and the in vitro display of the protein, therefore, fully meets the instant broadly claimed method.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

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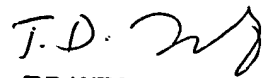
statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703) 308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

tdw

4/6/01


T.D. WESSENDORF
PRIMARY EXAMINER